

AMENDMENTS TO THE DRAWINGS:

In accordance with 37 C.F.R. § 1.121(d), the attached drawing sheets, each entitled "New Sheet" or "Replacement Sheet" and included in Appendix A, include Figures 1-4. Figures 1-3 were included in the originally-filed application and Figure 4 is submitted as a new drawing as required by the Examiner in the Office Action. Figures 1, 2 and 3 are submitted to replace the originally-filed Figures 1, 2 and 3 and are submitted only to correct sheet numbering. It is believed that no new matter is added as a result of the drawing amendments.

Attachments: New Sheet
Replacement Sheets

REMARKS/ARGUMENTS

This Amendment is submitted in response to the non-final Office Action mailed March 27, 2007 (the "Office Action"). Following entry of this Amendment, claims 1 and 4-21 remain pending in the application. Claims 1, 18 and 21 are independent.

In the Office Action, the Examiner:

- objected to the drawings under 37 C.F.R. § 1.83(a) for failing to show every feature of the invention specified in the claims;
- objected to claim 4 based on the "has a further transverse borehole" language;
- rejected claims 1-11, 13, 15, 16, 18 and 20 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim subject matter which the Applicant regards as the invention;
- rejected claims 1-3, 7, 9 and 13 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,077,264 to Chemello (hereinafter "Chemello");
- rejected claims 6 and 16 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chemello;
- rejected claims 1-8, 13 and 16 under § 103(a) as allegedly being unpatentable over German Patent No. 198 29 228 to Stedtfeld (hereinafter "Stedtfeld") in view of Chemello;
- rejected claim 14 under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello and further in view of U.S. Patent No. 5,356,410 to Pennig (hereinafter "Pennig");
- rejected claim 18 under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello and further in view of U.S. Patent No. 4,858,602 to Seidel *et al.* (hereinafter "Seidel");
- rejected claims 17, 19 and 20 under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello, further in view of Seidel and further in view of Pennig; and
- rejected claims 1-3, 9, 11 and 12 under § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,227,518 to Aginsky (hereinafter "Aginsky") in view of Chemello.

As outlined above, Applicants have amended claims 1, 4-11, 13, 15, 16, 18 and 20 to: address the objection to claim 4; address the 35 U.S.C. § 112, second paragraph rejections; better define the scope of the invention; more clearly distinguish over the cited art; and/or conform with amendments to other claims. New claim 21 was added to better define the scope of the invention. Claims 2 and 3 have been canceled without prejudice to their subsequent prosecution in any continuing application or disclaimer of the proprietary rights set forth therein. All amendments are fully supported by the originally-filed specification and/or drawings of the present application. In addition, as outlined in Appendix A, the figures have been amended to include new FIG. 4 and to correct sheet numbering as a result of the new figure. Lastly, as outlined above, the specification has been amended to include reference to new FIG. 4.

It is believed that no new matter has been added as a result of the amendments to the claims, figures and specification. The amendments made herein do not represent acquiescence in the Examiner's rejections, but rather are made only to expedite prosecution of the present application and/or maintain consistency in claim language. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications. As discussed more fully below, Applicants respectfully submit that each of the currently pending claims define features that are not disclosed, taught or suggested by the prior art of record and respectfully request allowance of same.

Drawing Objections

In the Office Action, the Examiner objected to the drawings for failing to show every feature of the invention specified in the claims. Specifically, the Examiner alleges that the bone plate and the medullary pin constructed as one piece as recited in claim 6 is not shown in the figures. In response, as outlined above, Applicants have added new FIG. 4 that shows the bone plate and the medullary pin constructed as a single piece. Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

Claim Objections

Claim 4 was objected to because of the phrase "has a further transverse borehole." In

response, as outlined above, Applicants have amended claim 4 to recite "the distal half of the intramedullary pin further includes a transverse borehole" as suggested by the Examiner. Accordingly, Applicants respectfully request that the objection to the claim 4 be withdrawn.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-11, 13, 15, 16, 18 and 20 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Regarding claims 1, 7, 16 and 20, the Examiner asserts that there is insufficient antecedent basis for "the pin" limitation. In response, as outlined above, Applicants have amended the claims to replace all references to "pin" with "intramedullary pin."

Regarding claims 2-6, 8-11, 13 and 15, the Examiner asserts that there is insufficient antecedent basis for the "medullary pin" limitation. In response, as outlined above, Applicants have amended the claims to replace all references to "medullary pin" with "intramedullary pin."

In addition, the Examiner asserts that claim 2 recites a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation in the same claim and specifically cites "an angle β of between $0^\circ + 100^\circ$ " as the broad limitation and also cites "preferably of between $+40^\circ$ and $+50^\circ$ " as the narrower range. Claim 3 was also rejected for similar reasons. Applicants believe that these rejections are in error because the recitations "preferably of between $+40^\circ$ and $+50^\circ$ " and "preferably of between -40° and -50° " were deleted from claims 2 and 3, respectively, in the previous Amendment. Furthermore, Applicants have canceled claims 2 and 3 and have amended claim 1 to include the limitations from claims 2 and 3, excluding any reference to " $+40^\circ$ and $+50^\circ$ " or " -40° and -50° ."

Further, claims 2 and 3 were also rejected under § 112, second paragraph, because the Examiner states that it is unclear if the limitation that the center of gravity of the angled tab of the bone plate, if projected onto a cross-sectional area orthogonal to the longitudinal axis of the medullary pin, lies on a radius which encloses in this cross-sectional area an angle β of between 0° and $+100^\circ$ or of between 0° and -100° relative to a projection of the transverse borehole axis, is a limitation applying to the bone plate, and accordingly, the Examiner has

treated these portions of claims 2 and 3 as functional language and *not* a limiting characteristic of the bone plate. In response, as outlined above, Applicants have canceled claims 2 and 3 and have amended claim 1 to include limitations similar to those recited in claims 2 and 3. Applicants respectfully submit that amended claim 1 clarifies the limitations for the bone plate.

Accordingly, based on the above claim amendments and remarks, Applicants respectfully request that the § 112, second paragraph, rejections be withdrawn.

Claim Rejections Under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a)

Claims 1-3, 7, 9 and 13 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chemello. In addition, claims 6 and 16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chemello; claims 1-8, 13 and 16 were rejected under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello; claim 14 was rejected under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello and further in view of Pennig; claim 18 was rejected under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello and further in view of Seidel; claims 17, 19 and 20 were rejected under § 103(a) as allegedly being unpatentable over Stedtfeld in view of Chemello, further in view of Seidel and further in view of Pennig; and claims 1-3, 9, 11 and 12 were rejected under § 103(a) as allegedly being unpatentable over Aginsky in view of Chemello. The rejections are traversed for at least the following reasons.

As recited in revised independent claim 1, the instant invention is directed to a bone fixation device comprising, *inter alia*, a bone plate that includes:

an angled tab configured and dimensioned to have a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β relative to a plane defined by the transverse borehole axis and the intramedullary pin's longitudinal axis, where angle β is between 0° and +100° or between 0° and -100°.

Applicants respectfully submit that the cited references fail to teach or disclose a bone fixation device with a bone plate having the characteristics specifically recited in the claims.

Bone plates are typically mounted at the proximal end of an intramedullary pin in order to transfer forces and moments acting on the head of the hip joint and the greater

trochanter to the intramedullary pin. Prior devices, such as described in Pennig, are disadvantageous in that the bone plate is disposed diametrically to the neck of the femur and protrudes distally beyond the hip screws. The instant invention remedies the problems associated with prior devices because the instant inventive device transfers an existing muscle force over the hip screw as well as over the bone plate, directly to the intramedullary pin and also does not transfer forces acting on the head of the hip joint to the bone plate and instead transfers these forces directly to the shaft of the femur. *Substitute Specification dated December 27, 2006*, page 1, lines 11-26.

One reason why the instant invention remedies the problems with prior devices is due to the geometry or shape of the bone plate. As disclosed, the bone plate comprises a distally angled tab, the center of gravity of which, if projected into a cross-sectional area orthogonal to the longitudinal axis of the medullary pin, lies on a radius that encloses an angle β of between 0° and $+100^\circ$ for a device to be used on the right femur and an angle β of between 0° and -100° for a device for the left femur. This arrangement permits the bone plate to be passed past muscles and ligaments disposed at the greater trochanter. *Id.* at page 2, lines 21-28. Further advantages achieved by the inventive device include: a resistance or counter-moment can be offered to the muscle forces that act on the greater trochanter, especially in the case of fractures of type 31 A3.2 of the AO (Association for Osteosynthesis) classification; and forces acting on the head of the hip joint, especially the force component acting parallel to the neck of the femur, can be transferred to the medullary pin. *Id.* at page 2, lines 9-16.

Accordingly, the center of gravity of the bone plate is a very important feature or characteristic of the inventive device.

As defined, the center of gravity is:

[a] fixed point in a material body through which the resultant force of gravitational attraction acts. The resultant of all forces or attractions produced by the Earth's gravity on a body constitutes its weight. This weight is considered to be concentrated at the center of gravity The location of the center of gravity for a body remains fixed in relation to the body regardless of the orientation of the body. If supported at its center of gravity, a body would remain balanced in its initial position.

McGraw-Hill Encyclopedia of Physics 116 (Sybil P. Parker ed., McGraw-Hill Book

Company 1983) (1982) (a copy of which is included in Appendix B). Therefore, the center of gravity of an object is specific to the geometry and weight of that object and hence, the relation of the center of gravity of the bone plate to the intramedullary pin is an important and critical characteristic, specific to the inventive device.

In paragraph 14 of the Office Action, the Examiner states that Chemello discloses a device wherein the bone plate has an angled tab with a center of gravity. While this is true because all objects have a center of gravity, Chemello fails to disclose the importance of the center of gravity and/or the specific relationship of the center of gravity of the angled tab to the intramedullary pin as recited in amended claim 1.

Further, in paragraphs 15 and 16 of the Office Action, when discussing claim 16, the Examiner states that either Chemello or, Chemello in combination with Stedtfeld, discloses the invention as claimed except for the center of gravity and the transverse borehole axis can be projected onto any cross-sectional area taken orthogonal to the longitudinal axis of the pin, wherein the angle β between the projection of the center of gravity and the projection of the transverse borehole axis is between -40° and -50° . The Examiner then asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone plate device of Chemello or the bone plate combination of Stedtfeld and Chemello wherein an angle β between the projection of the center of gravity and the projection of the transverse borehole axis is between -40° and -50° , because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In support of this assertion, the Examiner cites *In re Aller*, 220 F.2d 454 (C.C.P.A. 1955). Applicants respectfully disagree with the Examiner's statements and assertions for at least two reasons.

First, as discussed above, the claimed relationship between the center of gravity and the projection of the borehole axis being at an angle β of between $+40^\circ$ and $+50^\circ$ or between -40° and -50° , is used to define the location of the center of gravity of the angled tab with respect to the intramedullary pin, which is a significant structural aspect of the instant invention. It is not just that the center of gravity and the borehole axis *can* be projected as the Examiner seems to indicate in his statement.

Second, *Aller* is directed to a chemical process. In *Aller*, the claimed chemical process which was performed at a temperature between 40°C and 80°C and an acid

concentration between 25% and 70% was held to be *prima facie* obvious over a reference process that differed from the claims only in that the reference process was performed at a temperature of 100° C and an acid concentration of 10%. *See M.P.E.P. § 2144.05 (II)*. In contrast, the instant invention is not directed to a chemical process and instead is directed to a bone fixation device, which is in a completely different field of invention. Therefore, the facts in *Aller* and the facts in the instant application, are dissimilar. The M.P.E.P states:

[t]he Examiner must apply the law consistently to each application after considering all the relevant facts. If the facts of a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

M.P.E.P. §§ 2144 and 2144.04 (emphasis in original). Accordingly, because the facts in *Aller* and the facts in the instant application are not sufficiently similar and because, as previously discussed, the location of the center of gravity of the angled tab of the bone plate is a critical aspect of the inventive device, the Examiner's assertion that it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone plate device of Chemello or the bone plate combination of Stedtfeld and Chemello wherein an angle β between the projection of the center of gravity and the projection of the transverse borehole axis is between -40° and -50°, because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art based solely on *Aller*, is inappropriate.

Further, Applicants respectfully submit that Pennig, Seidel and Aginsky fail to correct the deficiencies of Chemello and Stedtfeld.

In order for a Section 102 rejection to stand, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Applying the law to the instant facts, because, as discussed above, the sections of Chemello relied upon by the Examiner in the Office Action do not provide for a an angled tab having a center of gravity lying on a radius of a cross-sectional area of the intramedullary pin taken orthogonally to the intramedullary pin's longitudinal axis and enclosing an angle β of between 0° and +100° or between 0° and -100° with a plane defined

by the transverse borehole axis and the intramedullary pin's longitudinal axis, the Section 102(b) rejections must fail as a matter of law. Accordingly, Applicants' attorneys respectfully request that the Section 102 rejections be withdrawn.

Additionally, in order to establish *prima facie* obviousness of a claimed invention, the prior art reference or references must teach or suggest all the claim limitations. *M.P.E.P.* § 2143.03 (citing *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974)). Therefore, because the combination of Chemello, Stedtfeld, Pennig, Seidel and Aginsky, at least fails to teach, disclose or suggest all of the instant claim limitations as outlined above, the Section 103 rejections must also fail as a matter of law. Accordingly, Applicants' attorneys respectfully request that the Section 103 rejections be withdrawn.

For at least the foregoing reasons, it is believed that revised independent claim 1 patentably distinguishes over the relied upon portions of Chemello, Stedtfeld, Pennig, Seidel and Aginsky, either alone or in combination, and is therefore allowable. Revised independent claim 18 and new claim 21 are similar in scope to revised claim 1 and are therefore allowable for similar reasons. Further, claims 4-17, which depend from claim 1 and claims 19 and 20, which depend from claim 18, are allowable as well. Accordingly, Applicants respectfully request that the anticipation and obviousness rejections be withdrawn, and that the pending claims be allowed.

Please note that because the outstanding non-final Office Action issued prior to both the Supreme Court's decision in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) and the USPTO's guidance memorandum dated May 3, 2007 regarding *KSR*, to the extent that another Office Action issues rejecting the claims under the *KSR* standard or in accordance with the guidance memorandum, Applicant respectfully requests that any further Office Action be non-final.

In view of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider pending claims 1 and 4-21 with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

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Should any additional fees be required by reason of this Amendment and Response,
please charge such fees to Jones Day deposit account no. 50-3013.

Respectfully submitted,

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